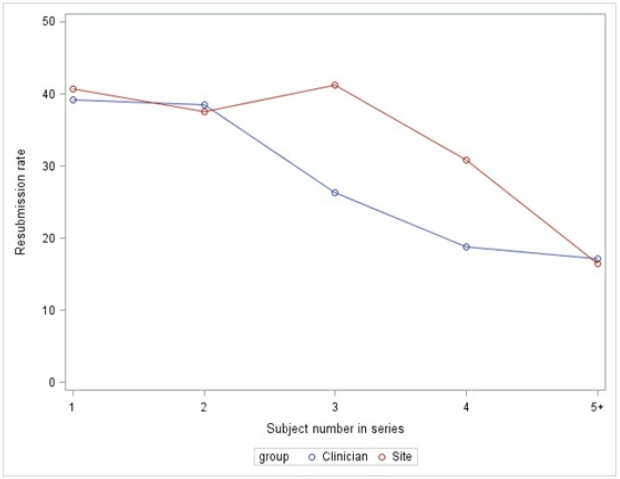
FIGURE 1. Rate of resubmissions in percent by subject number in series, at the clinician and site level.



Conclusions: Several low and high risk factors were identified which may assist with tailoring future clinical trial QA. RTR are essential due to a baseline level of resubmission, which is independent of clinician or site factors. There is a scope for modifying RTR QA to include only contouring RTR submissions at high volume sites. The lower rate of resubmission for cases using IMRT may be a surrogate for advanced technology implementation at a particular site.

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FMECA application to IORT procedure as a quality method to prevent and reduce patient's risk

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Purpose/Objective: Our Center acquired a mobile electron linear accelerator for intraoperative radiation therapy (IORT) and the clinical activity started at the end of June 2012. The risk assessment performed before the start of clinical activity was integrated with a predictive matrix risk analysis (FMECA). Two years later an analysis of all the relevant criticalities was performed in order to improve quality. The aim of this study is to present the results of the method elaborated by our Working Group and the application of FMECA prospective approach to IORT procedure.

Materials and Methods: A multidisciplinary Working Group was created, including different professional profiles. Each member of the Working Group was asked to identify a priori the criticalities he/she could meet in the process steps concerning his/her specific activity. In this way a list of all potential failure modes (FM) occuring in each process step was drafted.

The risk analysis was completed by asking the members of the team to evaluate the Risk priority number (RPN) of each FM.

Two years after the beginning of IORT clinical activity, the risk analysis was repeated by the Working Group, in order to assess the improvement achieved.

Results: The IORT process was subdivided in 43 steps and 39 criticalities were identified by the Working Group. They represented the issues prospectively investigated according to the FMECA method. An Excel worksheet was created, inserting in rows: process step, professional figures involved, failure mode, potential effects of failure, potential causes of failure, preliminary RPN and corrective actions. In the re-analysis of the process - two years later - the final RPN was elaborated and the risk reduction (RR) (preliminary RPN – final RPN) was also calculated, in order to assess the weight of the corrective measures. The highest score was attributed to the misalignement of the internal shield, used to protect the underlying normal tissues, with a risk reduction equal to 20 (25%) after corrective actions. The next critical scores were related to the inaccurate placement of the applicator in the tumour bed (RR: 28; 43,8%) and the wrong definition of the CTV (RR: 48; 75%). Another relevant failure mode was the inadequate placement of the dosimeter (gafchromic film) on top of the internal shield. In most cases this risk was prevented following the 'in vivo dosimetry' Procedure, elaborated by our Medical Physicist (RR: 28; 46.7%).

Conclusions: The FMECA technique has provided a prospective systematic method for discovering potential failures in IORT procedure; evaluating not only the frequency of FM but also their severity and detectability, it has given a more complete assessment of the risks. It contributes therefore to optimize patient safety right from the start of our clinical activity and to improve risk management culture among all the professionals involved in the Working Group.

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The definition of an auditable and complete dataset for lung cancer patients - the RTTís role

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Purpose/Objective: The North West area has one of the largest number of lung cancer patients in the U.K. Data collected for these patients relating to treatment outcome and graded toxicities does not currently allow us to accurately assess these data. In conjunction with a radiation oncology professor and a research fellow, an RTT has been heavily involved in the definition, production and design of a defined, auditable dataset for lung cancer patients.

Materials and Methods: Our institution is attempting to implement a data warehouse product into its information technology structure in order to make information more accessible to staff conducting audit and research. In the baseline assessments made during the set up of the data warehouse, the chair of radiation oncology appraised the data collected for patients and a decision was made to improve the quantity, and more importantly, the quality of the data recorded. On a disease site specific basis, and beginning with lung (a large patient group with poor outcomes), a work stream was set up in order to define an